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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,783	02/20/2004	Alan R. Klenk	MVMDINC.060A	6668

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/08/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/08/2007.

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Office Action Summary

Application No.

10/783,783

Applicant(s)

KLENK ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/5/06; 12/5/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendment received on 5 December 2006. The examiner acknowledges the amendments made to the claims.

The claim objection in the prior office action was in fact for Claim 20 (instead of Claim 29) regarding the informality of line 2 reading "the coil" and should instead read -- a coil--. Also, the examiner did in fact intend to object to Claim 26 in that it improperly limited the subject matter of Claim 20 (instead of Claim 1) regarding "a proximal releasably engaging the loading portion and a distal end releasably engaging the tissue piercing structure," although after receiving clarification in the response regarding the introduction of the structural element of the coil itself, the examiner finds that Claim 26 *does* further limit the subject matter of the independent Claim 20 and withdraws the objection.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 5 September 2006 and 5 December 2006 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1 and 9-10 are rejected under 35 U.S.C. 102(e) as being anticipated by **Gifford, III (“Gifford”)** (U.S. Pub. No. **20040267191**).

Claims 1 and 10: Gifford discloses delivering an elongate body **204** having a proximal end and a distal end to the patent foramen ovale, the elongate body having a tissue piercing structure at its distal end and a coil **200** releasably engaged with the elongate body, advancing the tissue piercing structure and the coil through the septa **SP**, **SS** of the patent foramen ovale, and releasing the coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, wherein the coil when released contracts to pinch the septum primum (“*sp*”) and septum secundum (“*ss*”) together (Figures 23A-23B, page 10, paragraph 98).

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Claim 9: Gifford discloses the elongate body being delivered through an outer catheter **202** (Figures 23A-23B).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) in view of **Pierson, III ("Pierson")** (U.S. Patent No. **6,663,633**).

Claim 2: Gifford discloses the claimed invention except for the elongate body having an opening near its distal end.

Pierson teaches an elongate body **40** having an opening near its distal end (Figure 1A). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an elongate body having an opening near its distal end, as taught by Pierson, to Gifford since it was known in the art an opening would allow the coil element to effectively engage with the elongate body without the use of a separate fastening or attachment device.

Claim 11: Gifford discloses the claimed device, including the coil being a first coil and releasing the first coil from the elongate body (see Claims 1 and 10 in paragraph 2 above), except for withdrawing the tissue piercing structure from the septa of the patent

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foramen ovale, advancing the tissue piercing structure and a second coil releasably engaged with the elongate body through the septa of the patent foramen ovale at a location adjacent to the first coil and releasing the second coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, wherein the second coil when released contracts to pinch the *sp* and the *ss* together. In other words, Gifford essentially discloses the claimed device except for withdrawing the tissue piercing structure from the septa and using a second coil adjacent to the first coil to draw the septa together.

Pierson teaches a first coil **12** and an adjacent second coil **12'** that draw the two ends of the tissue **90** together and withdrawing the tissue piercing structure **40** from the septa (Figures 1A-1E). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second coil to the septa of the patent foramen ovale, as taught by Pierson, to Gifford in order to provide a more secure closure of the *sp* and the *ss* by covering more surface area of the tissue.

Claims 12-19: Gifford discloses the claimed invention, including closing a patent foramen ovale having an *sp* and *ss* and advancing a coil over a single elongate body at least partially through the septa of the patent foramen ovale using a tissue piercing structure on the distal end of the elongate body to secure the *sp* and *ss* together, including advancing the coil first through either of the *sp* or *ss* and then through the other septum (see explanation for Claims 1 and 10 above), except for using a plurality of coils, or three coils, advanced sequentially through a single catheter.

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Pierson teaches advancing a plurality of coils **12** and **12'** to draw opposing sides of tissue **90** together through a single catheter (Figures 1A-1E and col. 7, lines 61-67, col. 8, lines 1-17). See discussion of Claim 11 above that recites this limitation using Pierson. It would have been obvious to one of ordinary skill in the art to provide the advancement of a plurality of coils through a single catheter, as taught by Pierson, to Gifford in order to facilitate the subsequent advancement of the second coil after the first coil without having to reload or use another device. It also would have been obvious to one of ordinary skill in the art to provide three coils to Gifford since it was known in the art that the use of multiple fasteners covers more surface area and strengthens the binding force and closure of tissue.

5. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Pierson, III ("Pierson")** (U.S. Patent No. **6,663,633**), as applied to Claim 2 above, and further in view of **Johnson** (U.S. Pat. No. **6,485,504**).

Claims 3 and 4: Gifford and Pierson disclose the claimed invention, including the coil being advanced through the patent foramen ovale, except for the coil having a distal end that releasably engages the opening in the elongate body near its distal end and a loading portion that releasably engages a proximal end of the coil, the coil being advanced while being engaged with both the loading portion and the opening near the distal end of the elongate body to axially elongate and radially reduce the coil.

Johnson teaches a coil **100** with a distal end that releasably engages the opening **116** in the elongate body **108** near its distal end and a loading portion (the proximal end of **108**) that releasably engages a proximal end of the coil, the coil being advanced while being engaged with both the loading portion and the opening near the distal end of the elongate body to axially elongate and radially reduce the coil, in order for the coil to fit into the hole in the tissue (Figures 24-26 and col. 19, lines 9-32). It would have been obvious to one of ordinary skill in the art to provide a coil that is releasably engaged at both proximal and distal ends to a loading portion and an opening in the distal end of the elongate body, respectively, to axially elongate and radially reduce the coil, as taught by Johnson, to the combined device of Gifford and Pierson in order to effectively narrow the coil in diameter to fit the hole in the tissue.

6. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**), as applied to Claim 1 above, and further in view of **Laufer** (U.S. Pub. No. **20040193194**).

Claims 5-7: Gifford discloses the claimed device, including delivering an elongate body to the patent foramen ovale, except for delivering a loading collar with the elongate body, the loading collar releasably engaging a proximal end of the coil, the elongate body configured to be rotatable and axially slideable relative to the loading collar.

Laufer teaches delivering a loading collar **864** with the elongate body **881a** or **881b**, the loading collar releasably engaging a proximal end of the coil, the elongate body configured to be rotatable and axially slideable relative to the loading collar.

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(Figures 14A-14B and page 6, paragraphs 114-115). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading collar with the elongate body that is releasably engaged to the proximal end of the coil, as taught by Laufer, to Gifford in order to protect and secure the proximal end of the coil and advance it towards the tissue while avoiding the need for another instrument to release the coil from the proximal end into the tissue.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Laufer** (U.S. Pub. No. **20040193194**), as applied to Claim 7 above, and further in view of **Johnson** (U.S. Pat. No. **6,485,504**).

Claim 8: Gifford and Laufer disclose the claimed device except for the elongate body being advanced relative to the loading collar prior to advancing the coil to axially elongate the coil. See paragraph 5 above for discussion of Claims 3 and 4 that recite this limitation using Johnson.

8. Claims 20-21, 26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) in view of **Kobayashi** (U.S. Pat. No. **6,375,671**).

Claims 20-21 and 26: Gifford discloses the claimed device, including a loading portion **204** adapted to releasably engage a distal end of a coil **200** and a distal structure (distal end of coil **200**) adapted to releasably engage a distal end of the coil

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200 using a tissue piercing structure that is integral with the tissue piercing structure for extending through a septum primum and septum secundum of a patent foramen ovale (see Claims 1 and 10 in paragraph 2 above), except for the loading portion adapted to releasably engage a proximal end of the coil and the loading portion holding the coil relative to the piercing structure to axially elongate and radially reduce the coil.

Kobayashi teaches a loading portion **4** adapted to releasably engage a proximal end of a coil **1** and the loading portion holding the coil relative to the piercing structure to axially elongate and radially reduce the coil (Figures 5-8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading portion that releasably engages a proximal end of a coil, as taught by Kobayashi, to Gifford in order to effectively narrow the coil in diameter to fit the hole in the tissue.

9. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**), as applied to Claim 21 above, and in further view of **Kay** (U.S. Patent No. **5,662,683**).

Claim 22: Gifford and Kobayashi disclose the claimed device except for the loading portion comprising a slot adapted to receive the proximal end of the coil.

Kay teaches a loading portion **30** comprising a slot **44** adapted to receive the proximal end of the coil **10**, which enables the surgeon to apply a force to the coil (Figure 7, col. 4, lines 49-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading portion comprising a slot, as taught by

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Kay, to Gifford and Kobayashi in order for the surgeon to apply a force to the coil, which facilitates its delivery to tissue.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**), **Kobayashi** (U.S. Pat. No. **6,375,671**), and **Kay** (U.S. Patent No. **5,662,683**) as applied to Claim 22 above, and further in view of **Pierson, III ("Pierson")** (U.S. Patent No. **6,663,633**).

Claim 23: Gifford, Kobayashi, and Kay disclose the claimed device except for the tissue piercing structure having an opening adapted to releasably engage the distal end of the coil. See Claim 2 above in paragraph 4 that recites this limitation using Pierson.

11. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**), as applied to Claim 20 above, and further in view of **Laufer** (U.S. Pub. No. **20040193194**).

Claims 24 and 25: Gifford and Kobayashi disclose the claimed device except for a loading collar, and the tissue piercing device being moveable relative to the loading collar, and the tissue piercing structure being provided on an elongate body extending through the loading collar.

Laufer discloses a loading collar **864** with the tissue piercing structure **881b** provided on an elongate body having a proximal end and a distal end, the elongate body extending through the loading collar (Figure 14B and page 6, paragraph 114). It

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would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading collar, as taught by Laufer, to Gifford and Kobayashi since it was known in the art that loading collars abut against the tissue to stabilize the surgical site and facilitate deployment of devices that engage with the tissue.

12. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**), as applied to Claim 26 above, and further in view of **Bolduc** (U.S. Patent No. **5,582,616**).

Claims 27-28: Gifford and Kobayashi disclose the claimed device except for the proximal and distal end of the coil comprising a tang that extends into a diameter defined by the coil.

Bolduc teaches a proximal end of a coil **110** comprising a tang **122** that extends into a diameter defined by a coil in order to connect it to a delivery mechanism (Figure 3). Although Bolduc does not disclose a similar tang on the distal end of the coil (Gifford does disclose a distal tang **201** in Figure 23A, although used as a barb), it would have been obvious to one of ordinary skill in the art to provide a tang on either or both ends of the coil to Gifford and Kobayashi in order to attach the coil to a delivery device so that it can be effectively secured before being attached to a tissue.

13. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gifford, III ("Gifford")** (U.S. Pub. No. **20040267191**) and **Kobayashi** (U.S. Pat. No. **6,375,671**),

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as applied to Claim 20 above, and further in view of **Pierson, III ("Pierson")** (U.S. Pat. No. **6,663,633**).

Claim 30: Gifford and Kobayashi disclose the claimed device except for the loading portion being adapted to releasably engage a plurality of coils.

Pierson teaches a loading portion **10** being adapted to releasably engage a plurality of coils (Figures 1A-1E and col. 7, lines 61-67, col. 8, lines 1-17).

See Claims 12-19 above in paragraph 4 that recite this limitation using Pierson.

Response to Arguments

1. Applicant's arguments with respect to Claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.
2. In regards to the Laufer reference, the applicant argues that the needle of Laufer is not used to create a passage for the insertion of the coil and that the coil is not an implant which is detached into the body, and therefore one of skill in the art would not look to the Laufer reference to meet these limitations. However, Laufer does have a tissue piercing structure that is capable of creating a passage for the insertion of a coil which is capable of advancing into the tissue. Therefore it would have been obvious to one skilled in the art to use Laufer since the device provides a more efficient tool in avoiding the use of separate tools for the utilization of the tissue piercing structure and the coil, which is an important aspect of the applicant's invention.
3. In regards to the Johnson reference, the applicant argues that the device of Johnson is intended for use with a pre-existing hole in tissue. However, the Johnson

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reference is currently used in the rejection above for modifying the Gifford reference which possesses a tissue piercing structure, and one skilled in the art would look to the Johnson reference to modify Gifford for the aspect of using a coil to approximate two portions of tissue together which effectively narrows the coil in diameter to fit the passage in the tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



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